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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/511,580	02/23/00	MASTROTOTARO J	PD-0329

023608
MINIMED INC. - PATENT DEPARTMENT
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NORTHRIDGE CA 91325-1219

QM12/0731

EXAMINER	
KREMER, M	

ART UNIT	PAPER NUMBER
3736	6

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/511,580	MASTROTOTARO ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 12-13, 15-16, 21, 23-26, and 34-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,068,536 to Rosenthal. Rosenthal discloses a custom calibration for near-infrared instruments for the measurement of blood glucose which includes obtaining a plurality of blood samples from an individual at predetermined time intervals and for a predetermined period of time as stated in column 2, lines 15-32. Blood glucose measurements for each blood sample are obtained and entered into the near-infrared instrument. Noninvasive near-infrared optical absorption measurements are taken concurrently through a body part and are recorded in the analysis instrument. Calibration regression analysis is performed which involves linearly interpolating the blood sample glucose measurements with the near-infrared optical measurements to custom calibrate the near-infrared instrument for the individual. In regard to claim 2, a self-monitoring glucose meter is used (column 3, lines 31-37). In regard to claims 3, 16, and 37, the calculation of calibration characteristics includes linear regression algorithms (column 5, lines 60-64). In regard to claims 7 and 24-26, the calibration procedure can be repeated over several days (column 4, lines 64-66). In

regard to claims 13 and 15, the optical measurements are recorded once per min. In regard to claims 38-42, Rosenthal teaches a monitor 1 with a glucose sensor (5,6, and 8) and processor 10 in Fig. 2 and another measuring device (SMGM glucose meter in Fig. 3).

3. Claims 1-2, 6-8, 11-15, 19-25, 34-36, and 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,507,288 to Bocker et al. Bocker et al. discloses a non-invasive sensor-analysis-system that is combined with an invasive analytical system operating with a reagent-based analyzing element (column 4, lines 2-65). The sensor-analysis-system includes a movable sensor unit worn on the body and a stationary central unit. The central unit is the evaluation instrument of the invasive element-analysis system and serves for calibrating the sensor-analysis sub-system. The invention is used by diabetics for monitoring glucose levels. The calibration of the device is disclosed in column 5, line 53 to column 8, line 3 of Bocker et al. In Fig. 2 of Bocker et al., the central unit 3 contains a measurement device 23 to measure a change in the analysis-element 12 correlating with the change of the concentration of the analyzed substance and generates electrical signals corresponding to the measurement value R of the change correlating with the concentration. By means of an evaluation curve which describes the functional relationship of the sought concentration C and the test value R, the evaluation electronics 24 computes the sought concentration C of the analyzed substance and feeds these element-analysis data C_A to the memory 26 where they are stored. Sensor unit 2 contains sensor operation device 32 connected to at

least one sensor 7 which measures at the patient body a parameter correlating with the glucose concentration and contains electronic components to process the received signal into a sensor measurement value S. The sensor evaluation-electronics device 33 computes analytical data (concentrations) C, by means of an evaluation curve C_S stored in the memory unit 35 from the measurement values S. Element-analysis data C_A are used to calibrate the sensor-analysis data C_S.

In regard to claims 1 and 15, Fig. 3 of Bocker et al. shows multiple reference values at time t_1 to t_5. In regard to claim 2, a reference value becomes available when the patient stabs his/her finger to obtain a drop of blood (column 7, lines 34-37). In regard to claims 6 and 19, the sensor calibration determines from the comparison of C_A and C_S a new corrected evaluation curve. In regard to claims 7 and 25, the patient is able at any time to make a calibration using an analysis-element 12 (column 7, lines 19-20) and an example of one or twice daily is given in column 7, lines 38-40. In regard to claims 8 and 22, the sensor unit can generate values continuously or at minute intervals (column 7, lines 42-48). In regard to claim 20, the new evaluation curve ascertained during calibration may be used to back-correct sensor data already stored in memory (column 7, lines 60-67).

4. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,497,772 to Schulman et al. Schulman et al. discloses a glucose monitoring system that continuously measures the glucose concentration in a patient's blood (column 2,

lines 26-32). The monitoring system is calibrated periodically once every 24 hours against a blood sample that has been independently analyzed by a reference method (column 3, lines 36-41).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,068,536 to Rosenthal. as applied to claims 3 and 16 in view of U.S. Patent 5,813,403 to Soller et al. Rosenthal does not teach that the linear regression used is the least squares linear regression. It is well known in the art that linear regression algorithms such as least squares fitting is used for x-y arrays of data points as stated in column 7, lines 11-13 of Soller et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the least squares linear regression as disclosed by Soller et al. in the linear regression of Rosenthal since it is well known in the art that the least squares fitting is used for x-y arrays of data points.

7. Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,068,536 to Rosenthal. as applied to claims 1 and 13 in view of U.S. Patent 5,830,133 to Osten et al. Rosenthal does not teach the use of non-linear regression. It is well known in the art that regression algorithms such as linear regression, stepwise regression, and partial least squares regression are used to develop a statistical correlation between measurements and variables being quantified and are considered functionally equivalent. An example of the interchangeability of linear and nonlinear regression is given in column 10, lines 57-67 of Osten et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the linear regression of Rosenthal for the nonlinear regression of Osten et al. since they are functionally equivalent and it has generally been held to be within the skill level of the art to substitute elements that are functionally equivalent.

8. Claims 9-10 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,068,536 to Rosenthal. as applied to claims 1 and 13 in view of U.S. Patent 6,049,727 to Crothall, and in view of U.S. Patent 5,885,211 to Eppstein et al. Rosenthal does not teach the step of shifting the data by a predetermined time factor. Crothall teaches a system that monitors blood glucose levels in interstitial fluid that includes light emitting sources and detectors for processing the spectra to determine concentration as stated in column 17, line 33 to column 18 line 53. Crothall also teaches in column 17, lines 13-32 that interstitial fluid has many

advantages over blood when measuring glucose levels. Interstitial fluid and gel have little or no hemoglobin and red blood cells which create artifacts in spectroscopic measurements. Red blood cells cause scattering. By measuring in interstitial fluid, other sources of potential artifacts such as artifacts from pulsating blood vessels in blood measurements may also be eliminated. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the optical sensor of Rosenthal for the interstitial fluid sensor of Crothall since interstitial fluid and gel have little or no hemoglobin and red blood cells which create artifacts in spectroscopic measurements. Eppstein et al. teaches in column 31, lines 28-40 that data sets of individuals are analyzed to determine the time shift required to achieve the maximum correlation between the interstitial glucose levels and the blood glucose levels. The worst case time lag for this set of subjects was only 13 minutes and the average time lag was only 6.2 minutes. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include a time lag between the interstitial fluid reading and the blood level reading since it is well known in the art that a time shift is used to achieve the maximum correlation.

9. Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,497,772 to Schulman et al. as applied to claims 13 in view of U.S. Patent 4,786,394 to Enzer et al. Schulman et al. teaches that there are subsequent recalibration steps (column 3, lines 36-41). Schulman et al. does not teach that

subsequent calibrations factors are calculated differently from the first calibration factor. Enzer et al. discloses an analyzer for blood chemistry that uses a one-point calibration for its electrodes. Enzer et al. further teaches that a two-point recalibration is initiated to ensure continued accuracy. The recalibrations by the one-point method would perform the same function as the recalibrations by the two-point method by ensuring continued accuracy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the recalibrations by the two-point method of Enzer et al. for the recalibrations by the one-point method of Schulman et al. since they are functionally equivalent and it has generally been held to be within the skill level of the art to substitute elements that are functionally equivalent. In regard to claim 28, Schulman et al. teaches in column 15, line 18 to column 18, line 27 that the single-point calibration includes an offset called INTERCEPT. In regard to claim 29, the two-point recalibration inherently includes a linear regression. In regard to claims 30-31, for two points, a non-linear regression or non-regression method would yield the same results as a linear regression method and is considered functionally equivalent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a non-linear regression method or a non-regression method for the two point recalibration method of Schulman et al. since they are functionally equivalent and it has generally been held to be within the skill level of the art to substitute elements that are functionally equivalent.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,088,608 to Schulman et al. that discloses an electrochemical sensor which includes electronic circuitry for automatically performing on a periodic basis specified intergrity test which verify the proper operation of the sensor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

ERIC F. WINAKUR
PRIMARY EXAMINER